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PATENT
Docket No. 509582000110

CERTIFICATE OF HAND DELIVERY

I hereby certify that this correspondence is being hand filed with the United States Patent and Trademark Office in Washington, D.C. on October 9, 2001.

Tamia M. Newman

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

David H. McDaniel

Serial No.: 09/876,157

Filing Date: June 8, 2001

For: ULTRASOUND ENHANCEMENT OF PERCUTANEOUS DRUG ABSORPTION

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents were previously submitted in an Information Disclosure Statement and/or Office

Action, directed to the related application Serial Number 09/087,146, filed May 29, 1998, and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R. §1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the application.

This Information Disclosure Statement is submitted:

☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

In the event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 509582000110. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 8, 2001

Respectfully submitted,

By: _____

Wayne C. Jaeschke, Jr.
Registration No. 38,503

Morrison & Foerster LLP
2000 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-1888
Telephone: (202) 778-1446
Facsimile: (202) 263-8396

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 509582000110	Application Number 09/876,157
Applicant: David H. McDaniel	
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Mailing Date	

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	7/10/84	4,458,678	Yannas et al.			
	2.	03/03/87	4,646,743	Parris			
	3.	12/19/89	4,888,354	Chang et al.			
	4.	6/05/90	4,930,504	Diamtopulos et al.			
	5.	11/13/90	4,969,912	Kelman et al.			
	6.	06/04/91	5,021,452	Labbe et al.			
	7.	03/30/93	5,198,465	Dioguardi			
	8.	11/30/93	5,266,480	Naughton et al.			
	9.	7/26/94	5,332,802	Kelman et al.			
	10.	11/22/94	5,336,498	Brannan et al.			
	11.	03/14/95	5,397,352	Burres			
	12.	8/29/95	5,445,146	Bellinger			
	13.	08/19/95	5,445,634	Keller			
	14.	10/24/95	5,460,939	Hansbrough et al.			
	15.	01/07/97	5,591,44	Boss, Jr.			
	16.	08/26/97	5,660,836	Knowlton			
	17.	08/26/97	5,660,850	Boss, Jr.			
	18.	09/09/97	5,665,372	Boss, Jr.			
	19.	05/26/98	5,755,752	Segal			
	20.	08/30/88	4,767,402	Kost et al.			
	21.	08/06/91	5,037,432	Molinari			
	22.	07/13/93	5,226,907	Tankovich			
	23.	08/03/93	5,231,975	Bommannan et al.			
	24.	06/13/95	5,423,803	Tankovich et al.			
	25.	06/20/95	5,425,728	Tankovich			
	26.	04/15/97	5,620,478	Eckhouse			

EXAMINER: (examiner) | DATE CONSIDERED:

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	27.	07/01/97	5,643,334	Eckhouse			
	28.	08/19/97	5,658,323	Miller			
	29.	09/23/97	5,669,916	Andersen			
	30.	11/04/97	5,683,380	Eckhouse et al.			
	31.	11/11/97	5,686,112	Liedtke			
	32.	05/19/98	5,752,949	Tankovich et al.			
	33.	10/06/98	5,817,089	Tankovich et al.			
	34.	12/01/98	5,843,072	Furumoto et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES	Translation NO
	35.	08/28/97	97/7751	South Africa				

OTHER DOCUMENTS *(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	36.	Lasers in Surgery and Medicine, 21:262-268 (1997), Improvement of Host Response to Sepsis by Photobiomodulation, Wei Yu et al. (marked up)
	37.	J. Dermatol. Surg. Oncol., 13:2, February, 1987, Biostimulation of Wound Healing by Lasers: Experimental Approaches in Animal Models and Fibroblast Cultures, R. Patrick Abergel et al. (marked up)
	38.	Lasers in Surgery and Medicine, 12:528-537 (1992), Power Density and Exposure Time of He-Ne Laser Irradiation are More Important than Total Energy Dose in Photo-Biomodulation of Human Fibroblasts in Vitro, Hans H.F.I. van Breugel et al.
	39.	Skin Barrier Principles of Percutaneous, Absorption, Hans Schaefer et al. 1996., pp.153 and 175 (marked up)
	40.	Skin Pharmacol, 1994; 7:130-139, High Frequency Sonophoresis: Permeation Pathways and Structural Basis for Enhanced Permeability, Gopinathan K. Menon et al. (marked up)
	41.	Anesthesiology, V. 78 No. 6, June 1993, Use of Ultrasound to Enhance the Local Anesthetic Effect of Topically Applied Aqeous Lidocaine, Katsuro Tachibana et al . (marked up)
	42.	Journal of the American Podiatric Medical Association, Vol. 82, No. 8, August 1992, Hydrocortisone Phonophoresis, A Literature Review, Joseph T. Newman et al. (marked up)

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	43.	Science, Vol. 269, August, 1995, Ultrasound-Mediated Transdermal Protein Delivery, Samir Mitragotri et al. (marked up)
	44.	Pharmaceutical Research, Vol. 8, No. 2, 1991, Influence of Ultrasound on the Percutaneous Absorption of Nicotinate Esters, Heather A. Benson et al. (marked up)
	45.	Physiotherapy, Vol. 74, No. 11, November, 1988, Transmission of Ultrasound Energy Through Topical Pharmaceutical Products, Heather A.E. Benson et al. (marked up)
	46.	Journal of Pharmaceutical Sciences, Vol. 84, No. 6, June, 1995, A Mechanistic Study of Ultrasonically-Enhanced Transdermal Drug Delivery, Samir Mitragotri et al. (marked up)
	47.	Pharmaceutical Research, Vol. 9, No. 8, 1992, Sonophoresis. II. Examination of the Mechanisms of Ultrasound-Enhanced Transdermal Drug Delivery, D. Bommannan et al. (marked up)
	48.	The International Congress of Esthetics, October 25-27, 1997, convention program
	49.	Cosmetics & Toiletries, Vol. 113, June, . 1998, Ultrasonic Radiation for Hair Treatments, Miklos M. Bruer
	50.	J. Appl. Cosmetol., Vol. 15, 147-159, Oct.-Dec. 1997, Enhancing the Glycolic Acid Efficacy by Piezoelectric Vibrations, P. Mortganti et al. (marked up)
	51.	Rheumatology and Rehabilitation, 1975, 14, 237, The Stimulation of Protein Synthesis in Human Fibroblasts by Therapeutic Ultrasound, W. Harvey et al. (marked up)
	52.	Physical Therapy, Vol. 75, No. 7, July 1995, In Vitro Effects of Therapeutic Ultrasound on the Nucleus of Human Fibroblasts, Patrick G. De Deyne et al.
	53.	The Lancet, July 25, 1987, A Controlled Trial Weekly Ultrasound Therapy in Chronic Leg Ulceration, M.J. Callam et al., pp.204-206 (marked up)
	54.	Am. J. Phys. Med. Rehabil., Vol. 68 No. 6, December 1989, The Effects of Therapeutic Ultrasound on Tedon Healing, Chukuka S. Enwemeka
	55.	Acta Chirurgiae Plasticae, 19, 3-4, 1977, Ultrasonic Effect on Collagen Synthesis and Deposition in Differently Localized Experimental Granulomas, J.E. Purkyne (marked up)
	56.	Infections in Surgery, September, 1982, Stimulation of Tissue Repair by Therapeutic Ultrasound, Mary Dyson
	57.	Arch Phys Med Rehabil., Vol. 73, July 1992, Low Dose Ultrasound Effects of Wound Healing: A Controlled Study with Yucatan Pigs, Nancy N. Byl, et al. (marked up)
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	61.	Ultrasound in Med. & Biol. Vol. 4 pp-343-351, The Role of Cavitation in the In Vitro Stimulation of Protein Synthesis in Human Fibroblasts by Ultrasound, D.F. Webster et al. (marked up)
	62.	J. Dermatol Sci., March 1996, 11(3):250-253, Ascorbic Acid Preferentially Enhances Type I and III Collagen Gene Transcription in Human Skin Fibroblasts, Takima S. Pinnel (Abstract)
	63.	J. Photocem Photobiol B, February 1993; 17(2):109-114, Photodynamic Effects on the Nuclear Envelope of Human Skin Fibroblasts, B. Krammer et al. (Abstract)
	64.	J. Biochem (Tokyo), November, 1984; 96(5)1491-1500, Hemoprotein H-450 Indentified as a Form of Cytochrome P-450 Having an Endogenous Ligand at the 6th Coordination Position of the Heme, T. Omura (Abstract)
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	66.	Vojnosanit Pregl., November, 1995; 52(6):539-546, Stimulatory Effect of Low-Power Density He-Ne Radiation of Human Fibroblasts in Vitro, M. Hrnjak et al. (Abstract)
	67.	Ann Plast Surg, January, 1987; 18(1):47-50, Biostimulation of Wound Healing in Vivo by a Helium-Neon Laser, R.F. Lyons et al. (Abstract)
	68.	Lasers Surg Med, 1997; 20(1):56-63, Effects of Photostimulation on Wound Healing in Diabetic Mice, W. Yu et al. (Abstract)
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	73.	Vojnosanit Pregl, November, 1995; 52(6):539-546, Stimulatory Effect of Low-Power Density Ne-Ne Laser Radiation on Human Fibrblasts in Vitro, M. Hrnjak et al. (Abstract)
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		Hamster Skin Flap Model Using a Specific ICG Formulation, S. Mordon et al.
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	78.	Pharmacuetical Research, 1992, Vol 9. pp. 629-635, Adsorption of Fluorescein Dyes on Albumin Microspheres, Kamel Egbaria et al.
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	80.	Journal of Pharmaceutical Sciences, Vol. 79, No. 6, 1990, Relationship Between Contact Time of Applied Dose and Percutaneous Absorption of Minoxidil from a Topical Solution, James Ferry et al.
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	83.	Science, Vol. 270, 1995, Chemical Generation Of Acoustic Waves: A Giant Photoacoustic Effect, Huxiong Chen et al.
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	85.	Journal of Pharmaceutical Sciences, Vol. 58, No. 9, 1969, Enhancement of Percutaneous Absorption by the Use of Volatile: Nonvolatile Systems as Vehicles, M.F. Coldman et al.
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	87.	Meth and Find Exp Clin Pharmacol, 1989; 11(10): 643-646, Percutaneous Absorption of Coumarin, Griseofulvin and Propranolol Across Human Scalp and Abdominal Skin, Wolfgang Ritschel et al.
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	89.	Arch Dermatol, Vol. 121, Feb. 1985, Percutaneous Absorption of Minoxidil in Man, Thomas Franz
	90.	Skin Pharmacol, 1991; 4:230-234, Percutaneous Penetration of Methyl Nicotinate at Three Anatomic Sites: Evidence for an Appendageal Contribution to Transport, Ethel Tur et al.
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		Flow, F. Hueber et al.
	93.	Journal of Pharmaceutical Sciences, Vol. 82, No. 2, 1993, Iontophoretic Transdermal Delivery of Salicylic Acid and Licodaine to Local Subcutaneous Structures, Pariminder Singh et al.
	94.	Arch Dermatol Res. 267, 229-235 (1980), Variations in Percutaneous Absorption of Testosterone in Rhesus Monkey Due to Anatomic Site of Application and Frequency of Application, Ronald Wester et al.
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	99.	Physiological Review, Vol. 51, No. 4, 1971, Permeability of the Skin, Robert Scheuplein et al.
	100.	Mag.-Bull, 1987, pp. 130-131, Noise-Induced Hearing Loss in Humans as a Function of Serum Mg Concentration, Z. Joachims et al.
	101.	Clin, Cardiol, 20, 285-290 (1997), Electrophysiology, Pacing and Arrhythmia, Dan Roden, MD
	102.	The Yale Journal of Biology and Medicine, 58 (1985), 553-559, Regulation of Collagen Biosynthesis by Ascorbic Acid: A Review, Sheldon Pinnell
	103.	Archives of Biochemistry and Biophysics, Vol. 295, No. 2, 1992, pp.397-403, Ascorbic Acid and Transforming Growth Factor-B1 Increase Collagen Biosynthesis via Different Mechanisms: Coordinate Regulation of Proa1(I) and Proa1(III) Collagens, Charlotte Phillips et al.
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	106.	Journal of Pharmaceutical Sciences, Vol. 80, No. 5, 1991, Follicles Plan an Important Role in Percutaneous Absorption, Brigette Illel et al.
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	108.	Ultrasound in Med. Biol., Vol. 22, No. 2, pp.151-164, 1996, Physical Characteristics and Biological Effects on Laser-Induced Stress Waves, A. Doukas et al.
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	110.	Lasers in Surgery and Medicine, 20:426-432, 1997, Effects of Low-Energy Gallium-Aluminum-Arsenide Laser Irradiation on Cultured Fibroblasts and Keratincytes, M. Pogrel et al.
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	112.	Electrotheraphy, Vol. 11, No. 4, July/August 1991, Ultrasound: Current Concepts, Nancy Gann
	113.	The Journal for Prevention and Healing Advances, Vol. 9, No. 5, Deptember/October 1996, Promotion of Wound Healing with Electrical Stimulation, Luther Kloth et al.
	114.	Advance for Physical Therapists, March 23, 1992, Iniformity Needed in Therapeutic Use of Ultrasound, Michelle Pronsati
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	116.	Reprint from the Journal, Physikalische Medizin und Rehabilitation Heft 9/68, The Combined Application of Ultrasound and Stimulation Currents, K. Gierlich et al.
	117.	Advance Rehabilitation, April, 1995, From Submarines to Rehab: New Developments in Ultrasound, John Murphy
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	119.	The Twentieth Annual Pharmaceutics Graduate Student Research Meeting, The University of Missour-Kansas School of Pharmacy, June 10-12, 1988, The Effect of Ultrasound on the In Vitro Penetration of Ibuprofen Through Human Epidermis, Maulik Nanavaty et al.
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